

REMARKS

Rejection of claims under 35 U.S.C. § 102

The Office maintained its rejection of claims 1, 2, 5-7, 9, 10, 30, and 31 as anticipated under 35 U.S.C. 102(b) by Moreau. The applicants respectfully traverse.

The present claims are directed to a pneumococcus type 5 capsular polysaccharide which is aminated on the terminal aldehyde group and is characterized by certain NMR and chromatography profiles, which signify that the aminated pneumococcus type 5 capsular polysaccharide is free of compound X contaminant. But Moreau fails to disclose any reductively aminated pneumococcus type 5 capsular polysaccharide, let alone one free of compound X.

The Office asserted that anticipation does not require the actual disclosure of working examples; it merely requires that the prior art contain adequate written description of the anticipated invention under the requirements of 35 USC § 112, and that Moreau does that. The applicants respectfully disagree; Moreau does not do that.

Nowhere in Moreau is there a teaching of a reductively aminated pneumococcus type 5 capsular polysaccharide, let alone an aminated pneumococcus type 5 capsular polysaccharide free of compound X. Moreau teaches a generic method of reductive amination of polysaccharides and states that it can be applied to any type of polysaccharide (col. 6, ll. 52-53), including a pneumococcus type 5 capsular polysaccharide (col. 6, ll. 60-61). But nowhere does Moreau teach a pneumococcus type 5 capsular polysaccharide that had been reductively aminated by the method of Moreau. That is, Moreau does not teach any aminated pneumococcus type 5 capsular polysaccharide, let alone one free of compounds X (as presently claimed). Disclosure of a generic chemical process and a genus of reactants and reaction conditions is not a description of a particular product of the process obtained with a particular reactant and particular reaction condition parameters.

Furthermore, the applicants disagree with the Office's characterization of the method of the present invention. At p. 5, ll. 3-7, the Office incorrectly concludes that "the critical element for suppressing the formation of compound X is in fact that the incubation time be no greater than 4 hours." (Emphasis added.) The Office based this conclusion on two teachings of the present specification, the embodiment presented in Example 1 and the passage on p. 17, l. 24 – p. 18, l. 7. But neither of these teachings state that the incubation time is the critical element.

Rather, the passage on p. 17, l. 24 – p. 18, l. 7 merely states that an incubation time of between 2 and 4 hours is recommended, and Example 1 provides a non-limiting example employing a 2 hour incubation time; neither of these teachings identify incubation time as the only parameter of the inventive method necessary to produce the claimed aminated polysaccharide.

As embodied in the withdrawn method claims, the compounds of the invention are produced by either of two methods, each of which comprises a combination of parameters:

1. (Claim 11) reductive amination in the presence of a reducing agent selective for a Schiff base at a pH of 4 to 6.5 (*i.e.*, acidic pH) for a period not exceeding 4 hours.
2. (Claim 15) (i) reacting the polysaccharide with an agent for reducing a ketone function, (ii) fragmenting the reduced polysaccharide, and (iii) reductively aminating the reduced and fragmented polysaccharide.

Moreau teaches neither combination. In particular, the Office points to col. 5, ll. 42-55 and Table 1 in col. 11. But while the passage at col. 5, ll. 42 – 55 includes a teaching of a reaction time of 15 min. – 4 hours, it relates to Moreau's method, which employs microwave irradiation and a pH somewhere in the range of 5 to 10 (*see* col. 4, ll. 10-13); it does not disclose a reaction time of 15 min. – 4 hours in combination with a reducing agent selective for a Schiff base at a pH of 4 – 6.5. And the results presented in Table 1 are for a process employing a reaction buffer at pH of 7.5 (*i.e.*, basic pH) with microwave irradiation for 15 min., 30 min, or 60 min. or in a 50°C water bath for 60 min or 48 hrs. Thus, none of the process used to produce the reductively aminated polysaccharides reported in Table 1 are the same as those of the present invention. And, moreover, neither portion of Moreau referred to by the Office teaches reductive amination of a pneumococcus type 5 capsular polysaccharide – (both portions involve *Salmonella typhi* Vi polysaccharide). Neither of these portions is a description of an aminated pneumococcus type 5 polysaccharide free of compound X.

For the foregoing reasons, therefore, Moreau cannot anticipate the present claims, and the applicants respectfully request reconsideration and withdrawal of this rejection.

Rejection of claims under 35 U.S.C. § 103

The Office maintained the rejection of 1-10, 30, and 31 as obvious over Moreau in view of Jansson. For the following reasons, the applicants respectfully traverse.

The Office first asserted at the bottom of page 6 of the Office Action that the recitation of the NMR and chromatography profile of the claimed compounds carried no patentable weight towards the claimed compound because they are considered to be inherent properties of aminated pneumococcus type 5 capsular polysaccharide. The applicants respectfully traverse. While the NMR and chromatography profiles are inherent properties of the *claimed* aminated pneumococcus type 5 capsular polysaccharides, they are *not* inherent properties of *all* aminated pneumococcus type 5 capsular polysaccharides. These profiles distinguish the claimed aminated pneumococcus type 5 capsular polysaccharides (which are free from compound X) from prior art aminated pneumococcus type 5 capsular polysaccharides (which are contaminated by compound X) and, as such, impart a patentable distinction.

The Office also asserted on page 7, ll. 2 – 4, of the Office Action that Moreau discloses aminated pneumococcus type 5 capsular polysaccharide. This is incorrect. Moreau discloses that pneumococcus type 5 capsular polysaccharide can be used in the method of the invention; Moreau not disclose an aminated pneumococcus type 5 capsular polysaccharide *per se*. More importantly, however, Moreau not disclose aminated pneumococcus type 5 capsular polysaccharide free of compound X.

And Jansson does not compensate for this fundamental deficiency. Jansson provides no teachings motivating or giving reason for an ordinary artisan to modify the method of Moreau in such a manner as to yield aminated pneumococcus type 5 capsular polysaccharide free of compound X. Thus, combining Jansson with Moreau does not result in the presently claimed polysaccharides.

Neither Moreau nor Jansson recognize that compound X is a contaminant of aminated pneumococcus type 5 capsular polysaccharide made by prior art methods. Without such a recognition, there can be no reason or motivation to modify Moreau's teachings to eliminate compound X from the aminated pneumococcus type 5 capsular polysaccharide product, nor could there be any teaching of how to do it.

For all of foregoing reasons, the applicants respectfully request reconsideration and withdrawal of this obviousness rejection.

In view of the foregoing amendments and remarks, the applicant submits that the claims are in condition for allowance, which is respectfully solicited. If the examiner believes a

teleconference will advance prosecution, he is encouraged to contact the undersigned as indicated below.

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